K070791
P1/4

510(K) SUMMARY

JUN 26 2007

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____.

Submitter:

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- **Contact Person:**

Li Dongling
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Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

- **Date Prepared:**

March 7, 2007

Name of the devices:

- **Trade/Proprietary Name:** PM Series Patient Monitors (Including Models PM-9000 Express and PM-8000 Express)
- **Common Name:** Patient Monitor
- **Classification**

21 CFR 870.1025	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Class II
21 CFR 870.1025	Detector and Alarm, Arrhythmia	Class II
21 CFR 870.1025	Monitor, ST Segment with Alarm	Class II
21 CFR 870.2300	Cardiac monitor (including cardiotachometer and rate alarm)	Class II
21 CFR 870.1130	Non-Invasive blood pressure measurement System	Class II
21 CFR 870.1110	Blood pressure computer	Class II
21 CFR 880.2910	Clinical Electronic Thermometers –	

0035

	Temperature Monitor with Probe	Class II
21 CFR 870.2700	Oximeter, Pulse	Class II
21 CFR 870.2710	Ear Oximeter, Pulse	Class II
21 CFR 868.1400	Carbon Dioxide Gas Analyzer	Class II
21 CFR 868.1500	Enflura ne gas analyzer	Class II
21 CFR 868.1620	Halothane gas analyzer	Class II
21 CFR 868.1700	Nitrous Oxide gas analyzer	Class II
21 CFR 868.1720	Oxygen gas analyzer	Class II

Legally Marketed Predicate Devices:

1) K#053234, PM-9000 Express Patient Monitor, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
2) K#032858, IntelliVue MP60 and MP70 Patient Monitors, Philips Co., Ltd.
3) K#012467, SOLAR 8000M SYSTEM, GENERAL ELECTRIC MEDICAL SYSTEMS INFORMATION TECH.
4) K#020550, Passport 2 Vital Signs Monitor with View 12 ECG Analysis Module, Datascope Corp.
5) K#053193, PM-8000 EXPRESS PATIENT MONITOR, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.

Description:

The PM Series Patient Monitors including models PM-9000 Express and PM-8000 Express are battery or line-powered patient monitors. The patient monitors acquire the physiological signals such as ECG, respiration (RESP), non-invasive blood pressure (NIBP), saturation of pulse oxygen (SpO_2), temperature (TEMP), invasive pressure (IBP), carbon dioxide (CO_2) and anaesthetic gases (AG, PM-9000 Express only). These physiological signals are converted into digital data and processed. The monitors examine the data for alarm conditions and present them on the color TFT display. The monitors also provide advantageous operating control for the user. The optional built-in recorder, the optional CF memory card provides hard copies of all digital data and waveforms as well as tabular and graphic trend information, and storage the previous monitoring data information when power off accidentally.

Statement of intended Use:

The PM Series Patient Monitors including models PM-9000 Express and PM-8000 Express are intended to be used for monitoring, recording, and alarming of multiple physiological parameters in health care facilities by qualified health care professionals trained in the use of the equipments.

The physiological parameters that can be monitored by PM-9000 Express Patient Monitor are:

ECG(3-lead or 5-lead or 12-lead selectable), arrhythmia detection, ST Segment analysis, Heart Rate(HR), Respiration Rate(RESP), Non-invasive Blood Pressure (NIBP), Pulse Oxygen Saturation (SpO_2), Temperature (TEMP), Invasive Blood Pressure(IBP), Pulse Rate(PR), Carbon Dioxide (CO_2), and Anaesthetic Gases(AG).

The physiological parameters that can be monitored by PM-8000 Express Patient Monitor are: ECG(3-lead or 5-lead selectable), arrhythmia detection, ST Segment analysis, Heart Rate(HR), Respiration Rate(RESP), Non-invasive Blood Pressure (NIBP), Pulse Oxygen Saturation (SpO_2), Temperature (TEMP), Invasive Blood Pressure(IBP) and Pulse Rate(PR), and Carbon Dioxide (CO_2).

Their design allows the operator to adjust the settings of parameter alarms that audibly and visually notify the operator when an excursion occurs.

The target populations are human patients ranged from adult to neonate with the exception of the arrhythmia detection and ST segment analysis, for which the target populations are adult and pediatric only.

The PM Series Patient Monitors are not intended for use in a patient's home or residence, or when it has not been ordered by a physician.

Comparison of Technological Characteristics:

The modified devices are substantially equivalent to systems currently marketed predicate devices. The design, components, storage technology and energy source of the modified devices are similar to the predicate devices. Both the modified devices and the predicate devices provide a means for interfacing with a patient, collecting parameter specific physiological data, and processing the data for alarm generation and display of numeric values and waveforms on a bedside or central monitoring system. The parameters' specifications and technologies of the modified device are similar to the predicate devices.

The technological differences do not affect the safety or efficacy of the devices. Any safety issues that may be raised by software controlled medical devices are the same issues already addressed by the predicate devices and are addressed in the systems hazard analysis and in the system validation.

Testing:

Bench testing has been conducted to validate and verify that the PM Series Patient Monitors including models PM-9000 Express and PM-8000 Express meet all design specifications and are substantially equivalent to the predicate devices. The testing consisted of all environmental testing identified in the FDA's DCRND November 1993 "Reviewer Guidance Document for Premarket notification Submissions" Draft Guidance Document. Additional testing of ECG portion of the system has been performed to demonstrate compliance with the

ANSI/AAMI EC13-2002, "Cardiac monitors, heart rate meters, and alarms" and AAMI EC57-98, "Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement Algorithms". Additional Testing of the Carbon Dioxide (CO_2) portion of the system has been conducted according to the requirements outlined in the Standards ISO 21647-2005, "Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors".

Finally, a hazard analysis of the systems and their software have been performed and testing has been conducted to validate the systems overall operation. The PM Series Patient Monitors including models PM-9000 Express and PM-8000 Express have also been tested to assure compliance with the requirements of various published standards, including ISO9919, IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-4, IEC60601-2-27, IEC60601-2-30 and ISO14971, etc..

Conclusion:

The conclusions drawn from clinical and bench testing of the PM Series Patient Monitors including models PM-9000 Express and PM-8000 Express demonstrate that the devices are as safe, as effective, and performs as well as or better than the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2007

Shenzhen Mindray Bio-medical Electronics Co., LTD
c/o Mr. Li Dongling
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan,
Shenzhen, 518057, P.R. China

Re: K070791
PM Series Patient Monitors
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: May 30, 2007
Received: June 1, 2007

Dear Mr. Dongling:

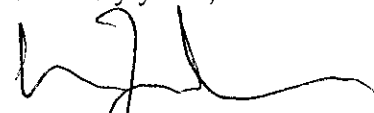
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070791

Indications for Use

510(k) Number (if known): _____

Device Name: PM Series Patient Monitors

Indications for Use:

The PM Series Patient Monitors including models PM-9000 Express and PM-8000 Express are intended to be used for monitoring, recording, and alarming of multiple physiological parameters in health care facilities by qualified health care professionals trained in the use of the equipment.

The physiological parameters that can be monitored by PM-9000 Express Patient Monitor are: ECG(3-lead or 5-lead or 12-lead selectable), arrhythmia detection, ST Segment analysis, Heart Rate(HR), Respiration Rate(RESP), Non-invasive Blood Pressure (NIBP), Pulse Oxygen Saturation (SpO2), Temperature (TEMP), Invasive Blood Pressure(IBP), Pulse Rate(PR), Carbon Dioxide (CO2), and Anaesthetic Gases(AG).

The physiological parameters that can be monitored by PM-8000 Express Patient Monitor are: ECG(3-lead or 5-lead selectable), arrhythmia detection, ST Segment analysis, Heart Rate(HR), Respiration Rate(RESP), Non-invasive Blood Pressure (NIBP), Pulse Oxygen Saturation (SpO2), Temperature (TEMP), Invasive Blood Pressure(IBP) and Pulse Rate(PR) , and Carbon Dioxide (CO2).

Their design allows the operator to adjust the settings of parameter alarms that audibly and visually notify the operator when an excursion occurs.

The target populations are human patients ranged from adult to neonate with the exception of the arrhythmia detection and ST Segment analysis, for which the target populations are adult and pediatric only.

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070791